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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,242	04/13/2004	Daniella I. Zheleva	CCI-014CP2	9212
959 7590 07/12/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER NIEBAUER, RONALD T	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/771,242

Applicant(s)

ZHELEVA ET AL.

Examiner

Ronald T. Niebauer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/2/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-55, 57-66 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) 51-55, 57-66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-50, 69, 71-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to the examiner's contact information listed at the end of this action.

Election/Restrictions

In the reply dated 5/2/07 applicants acknowledge the election of Group 142 and the species of SEQ ID NO:295 as set forth in the responses of 11/9/05 and 11/29/05. Claims 1-48,56,67-68 are cancelled.

Claims 51-55,57-66,70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Section 803.03 of the MPEP states:

'If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.'

In the instant case the elected species was not found allowable (see priority section below). Claims that read on a replacement or substitution are distinct from the elected species and held withdrawn.

Claims 49-50,69,71-73 are under consideration.

Priority

Applicant has noted that the current application is a continuation-in-part of previous applications and has noted that support for the amendments to claims 49-51 can be found throughout the specification, for example at page 33 lines 22-25 and at page 35 lines 1-5 and in

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the claims as originally filed for example claims 67-68. However, the claims as amended (49-51 and dependent claims) recite a particular subgenus that is not supported by the original application. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). Page 33 lines 22-25 recite a condition for X₉, but do not recite the subgenus of the current claims. For example, page 33 lines 10 and 13 support a peptide in which R is replaced and X₆ is replaced. However, claims 49-50 support a subgenus in which R can be unchanged (i.e. does not agree with original disclosure of R is replaced). Claims 49-51 support a subgenus in which X₆ can be unchanged (i.e. does not agree with original disclosure of X₆ is replaced). Although applicants claim support from claims 67-68 as originally filed, there were no claims 67-68 as originally filed. Hence, claims 49-55, 57-66, 69-70 do not receive the priority date of the originally filed application.

It is noted that claims 71-73 are supported by the original disclosure (page 35 of specification 2/2/04 and page 39 of specification 5/19/03).

Claim Objections

Claims 49-50, 69, 71-73 are objected to because of the following informalities:

Claims 71-73 are objected to for not ending in a period. MPEP § 804.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used

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elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).”

Claims 49-50,69,71-73 are objected to for inconsistent nomenclature. Claims 49 and 50 use the abbreviation pFPhe, claims 71-73 use the abbreviation PFF, and claim 71 uses the abbreviation pFF. Claims 49 and 50 use the abbreviation mClPhe, claims 71-73 use the abbreviation MCIF, and claim 71 uses the abbreviation mClF.

Claims 71-73 are objected to for improper Markush language. Section MPEP 2173.05(h) of the MPEP states:

‘When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if “wherein R is a material selected from the group consisting of A, B, C and D” is a proper limitation, then “wherein R is A, B, C or D” shall also be considered proper.’

In the instant case the claims are missing the term ‘or’/’and’.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-50,69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to a peptide of SEQ ID NO:293 which as defined on page 32 of the specification (line 22) states that X₉ is Phe. However, as currently recited in claims 49-50,69 the peptide of SEQ ID NO:293 has X₉ being an amino acid other than Phe.

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Further, claim 50 recites a condition in which R is substituted. If R is substituted how can the peptide consist of SEQ ID NO:293?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-50,69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Section 2163 of the MPEP states:

Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.

In the instant case an RCE has been filed, which is not the filing of a new application (MPEP 706.07(h)), with claims that are not supported in the original disclosure. Applicant has noted that the current application is a continuation-in-part of previous applications and note that support for the amendments to claims 49-51 can be found throughout the specification, for example at page 33 lines 22-25 and at page 35 lines 1-5 and in the claims as originally filed for example claims 67-68. However, the claims as amended (49-51 and dependent claims) recite a particular

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subgenus that is not supported by the original application. Page 33 lines 22-25 recite a condition for X₉, but do not recite the subgenus of the current claims. For example, page 33 lines 10 and 13 support a peptide in which R is replaced and X₆ is replaced. However, claims 49-50 support a subgenus in which R can be unchanged (i.e. does not agree with original disclosure of R is replaced). Claims 49-51 support a subgenus in which X₆ can be unchanged (i.e. does not agree with original disclosure of X₆ is replaced). Although applicants claim support from claims 67-68 as originally filed, there were no claims 67-68 as originally filed. Hence, claims 49-55, 57-66, 69-70 are not described by the originally filed application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49,50,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 2005/0260730). Note that the publication date of 11/24/05 qualifies as 102(b) art because claims 49,50,69 have the priority date of 5/2/07 (see above 'priority' and 'written description').

Briefly, claims 49,50,69 are drawn to a peptide of a particular sequence.

Fischer teach a peptide (section 0015 SEQ-ID NO:4) and acetylation of peptides (section 0104) which meets the claim limitations.

Claims 50,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Brinker et al. (European Journal of Biochemistry August 2000). Note that the publication date of 8/05 qualifies

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as 102(b) art because claims 50,69 have the priority date of 5/2/07 (see above 'priority' and 'written description').

Briefly, claims 50,69 are drawn to a peptide of a particular sequence.

Brinker teach a peptide (Page 5088, Table 2 peptide 1; abstract) of sequence RKLLW which can be acetylated (page 5086 line 28) which meets the claim limitations (note that L is a conservative substitution for I).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 71-73 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 20,21, 22 of copending Application No. 11/407,880. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-50,69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16,17,18,23 of copending Application No. 11/407,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims support peptide variants, some of which fall in the scope of the current invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Copending patent applications 09/726,470 and 10/441,952 are noted of interest. As presently claimed a double patenting rejection is not necessitated but some of the claims are similar in scope.

Conclusion


No claims are allowed. The elected species SEQ ID NO:295 is free of the art (based on priority date of 5/19/03), with prior art preceding a priority date of 5/2/07 (see 102 rejection).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn


Andrew D. Kosar
Patent Examiner, Art Unit 1654